

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Interstate Movement
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Dr. Frisby Smith	PERMIT NUMBER:	P526P-20-03360
ORGANIZATION:	Bayer US - Biologics	APPLICATION NUMBER:	P526-200617-048
ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	FACILITY NUMBER:	N/A
MAILING ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	HAND CARRY:	No
PHONE:	916-661-3322	DATE ISSUED:	08/06/2020
FAX:		EXPIRES:	08/06/2023
DESTINATION:	Bayer US - Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605		
RELEASE:	No		

Under the conditions specified, this permit authorizes the following:

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Yersinia entomophaga	Lyophilized plant or microbes, Microbial solutions, Petri dishes/culture tubes	Research - Greenhouse (growth chamber and lab included)	VA	Originally Collected from Foreign Locations	MH96 New Zealand
Yersinia entomophaga	Lyophilized plant or microbes, Microbial solutions, Petri dishes/culture tubes	Research - Greenhouse (growth chamber and lab included)	VA	Originally Collected from Within the Continental U.S.	Novozymes US isolates

PERMIT GUIDANCE

- 1) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.
- 2) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_an_products.shtml

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PPQ HEADQUARTER OFFICIAL VIA EPERMITS.



Robert Pfannenstiel

DATE

08/06/2020


WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

- 3) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 4) This permit DOES NOT fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 5) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

This permit authorizes the interstate movement of any life stages (cultures) of *Yersinia entomophaga* from Virginia to the permit holder, Dr. Frisby Smith, Bayer US - Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605, for research in the laboratory and greenhouse facilities at that address, subject to the conditions below.

1.
 - This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
 - The permit number or a copy of the permit must accompany the shipment.
 - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
 - You are legally responsible for complying with all permit requirements and permit conditions.
 - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
 - Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.
2. The permit holder must:
 - maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,

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- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.

3. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
4. The permit holder must insure that all persons working with these regulated organisms are informed of these permit conditions, have a copy of the permit, and understand the requirement to adhere to these conditions.
5. The regulated organisms authorized for import under this permit are to be maintained only in the laboratory area and greenhouse and associated facilities at Bayer US - Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605. Distribution or dissemination to other sites beyond/outside this location requires a separate prior authorization from APHIS PPQ (a PPQ 526 Permit), or amendment to this permit.

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Procedures must be in place to retain the regulated articles (permitted cultures) and media and substrate exposed to the cultures and inoculum during testing and screening, such as soil, pots and plants, and subject all such materials, inoculum and cultures of the species imported under this permit to procedures which will effectively devitalize the organisms and or properly dispose of these items as per adopted and approved laboratory protocols.

This permit does not authorize field release, interstate transport, field research, or other such activities in the natural environment with the regulated organisms authorized under this permit .


6. Upon receipt of imported package(s) and removal of organisms regulated under this permit, the primary shipping containers and any packing material media in the primary container, shall be properly disposed of or destroyed immediately. Procedure for proper disposal or destruction: all material must be double bagged, and then either sterilized by autoclave, or other established laboratory procedures, such that material is effectively devitalized and sterilized, or placed in a municipal landfill.

Only secondary containers and packing materials suitable for re-use (such as coolers and icepacks) may be reused, and only after sterilization by autoclave, or with bleach or alcohol, etc., as per protocols established and adopted for this facility.

7. All activities and procedures must be conducted in restricted access areas not accessible to unauthorized persons through locking (key, key card or code) of areas, rooms and associated equipment and storage areas where the organisms, or preparations containing the organisms are kept, or other effective method of restriction.
8. A separate authorization from USDA APHIS (a new PPQ 526 permit) is required for possession/maintenance of live regulated organisms received under this permit beyond the expiration of this permit. Otherwise, all regulated organisms possessed under this permit must be devitalized prior to expiration of this permit.

END OF PERMIT CONDITIONS

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